

K992855 (P.1 of 2)

510(k) Summary

1.0 Date Prepared
August 20, 1999

2.0 Submitter (Contact)
David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name
Proprietary Name: XPS StraightShot or Model 2000 Microdebrider System
or XPS PowerSculpt
(The proposed product tradename has not been finalized
and may be changed at a later date)

Common Name(s): Electrical surgical debridors, Tissue aspirator, Suction
lipoplasty system and cannula

Classification Name: Surgical instrument, AC powered motors and
accessories / attachments
Suction lipoplasty system

5.0 Device Classification
Surgical instrument, AC powered motors and accessories / attachments
ProcCode 87HWE Class II ; 21 CFR 878.4820 Tier 1

Suction lipoplasty system
ProcCode 79MFF Class II ; 21CFR 878.5040 Tier 2

6.0 Device Description

The Power Control Unit, handpiece and principle of operation remain essentially the same as described in K984363. The standard blades that are used for tissue debridement and aspiration will be replaced by suction cannulae equivalent in design to predicate suction lipoplasty cannulae. Lastly, a removable adapter, similar to the adapter cleared for rasping in K983025, will be provided to translate the rotary action of the handpiece to a reciprocating action. The

resulting reciprocation will facilitate the movement of the cannula through the adipose tissue.

7.0 **Intended Use**

The Xomed XPS / PowerSculpt System with reciprocating adapter and suction cannulas are intended for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty for aesthetic body contouring.

8.0 **Substantial Equivalence**

The XPS/PowerSculpt System, with expanded indications for suction lipoplasty, is substantially equivalent to the following predicate devices that are currently marketed to dissect and remove adipose tissue:

Powered Systems

MicroAire PAD-100 "Power Aspiration Device" (MicroAire Surgical Instruments)	K981922
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NuMED Power Cannula (NuMED or United American Medical)	510k unknown
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Aspiration Cannulae

Various cannulae (and aspirators) (Wells Johnson Company)	K832520
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Like the predicate powered systems, the XPS/PowerSculpt System consists mainly of a console, a handpiece and disposable cannulae. Currently, an adapter is proposed for use with the current XPS handpieces, to convert the rotary action of the handpiece to a reciprocating action. The end result and performance though is equivalent to the predicate devices..

As with the predicate devices, the small (approx. 3 mm), but rapid reciprocation of the cannula simulates the manual motion of the surgeon using a standard aspiration cannula. Not only does this reduce the manual effort required by the surgeon, it facilitates the penetration of the cannula through the tissue.

The XPS/PowerSculpt System is substantially equivalent to the currently marketed predicates as it has the same intended use and the same technological characteristics as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2000

Mr. David Timlin
Manager, Regulatory Affairs
Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216-0980

Re: K992855
Trade Name: XPS/PowerSculpt System
Regulatory Class: II
Product Code: MUU
Dated: December 8, 1999
Received: December 14, 1999

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.


A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. David Timlin

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992855

Device Name: XPS / PowerSculpt System

Indications for Use:

The XPS/PowerSculpt System with reciprocating adapter and suction cannula is indicated for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty for aesthetic body contouring.

(Please do not write below this line - continue on another page if needed)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-the-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992855